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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/625,930

07/23/2003

Charles E. Crutchfield

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9475

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05/25/2006

BRIGGS AND MORGAN P.A.

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/625,930	CRUTCHFIELD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sharmila S. Gollamudi	1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application. /
- 4a) Of the above claim(s) 1-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 7-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group II, claims 7-15 in the reply filed on 3/14/06 is acknowledged. Claims 1-6 are withdrawn as being directed to a nonelected invention.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claim 7 is rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Strauss (6,503,013).**

Strauss discloses a method of applying a medicament and a swab applicator. The applicator assembly comprises a swab applicator and a sealed compartment (ampoule), which contains the medicament medium. The medicament is released by pushing down on the adjustable member so that the interference is removed and the medicament is permitted to flow into contact with the applicator instrument. Specifically, Strauss discloses treating one or more warts wherein the sealed compartment comprises a solution of monochloroacetic acid. After preparing the wart, the swab applicator is activated by pressing the absorbent swab downward causing the solution of monochloroacetic acid to come into contact with the swab 20. The swab is

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then contacted with the area to be treated. After use, the swab applicator is conveniently disposed of along with other medical waste. See example 2.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Johnson et al (5,445,462).**

Johnson disclose a liquid applicator comprising an elongated hollow body having opposed first and second open ends in fluid communication with one another, and a tip attached to the first open end and including a porous material. A closed, frangible ampoule is supported within the second open end of the body and contains a liquid to be dispensed. A cap is provided at the second open end of the body, and which is movable axially relative to the body between a storage position and a use position in order to fracture the ampoule. See abstract. Johnson discloses an example of a particular use for an applicator capable of applying fluid to a very small treatment area exists in the treatment of exophytic genital and anal warts. Johnson discloses that typically wart treatment include cryotherapy with liquid nitrogen and treatment with a variety of different fluids including but not limited to Podofilox or Podophyllotoxin, silver nitrate, alcohol, TCA (trichloroacetic acid), podophyllin, or topical fluorouracil. See column 1, lines 49-67. The device delivers the medicament to the treatment area without spreading to surrounding tissues and is designed for single use.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al (5,445,462) in view of Coskey (Pediatric Dermatology, 1984 July; 2(1):71-3) in further view of Material Safety Data Sheet on podophyllin- salicylic acid-cantharidin mixture (5/3/00).**

The teachings of Johnson et al have been set forth above. Specifically, Johnson teaches the use of medicaments for warts include Podofilox or Podophyllotoxin, silver nitrate, alcohol, TCA (trichloroacetic acid), podophyllin, or topical fluorouracil. See column 1, lines 49-67.

Johnson does not specify the instantly claimed wart composition.

Coskey teaches the use of a topical preparation comprising 30% salicylic acid, 5% podophyllin, and 1% cantharidin in a film-forming base for the treatment of plantar warts. See abstract.

Material Safety Sheet teaches the composition podophyllin- salicylic acid-cantharidin mixture comprises 30% salicylic acid, 5% podophyllin, 1% cantharidin, 40% acetone, and 24% of a flexible collodion solution comprising ethyl ether, ethanol, bitter almond oil camphor (benzoin), castor oil, and pyroxylin.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Johnson et al, Coskey, and Material Safety Data Sheet on podophyllin- salicylic acid-cantharidin mixture, and utilize the instant wart composition. One would have been motivated to do so since Johnson teaches a device that provides accurate treatment of warts with medicaments including podophyllin and Coskey teaches a mixture of podophyllin-salicylic acid-cantharidin mixture is effective in treating plantar warts. Therefore, a skilled artisan would have been motivated to utilize the instantly claimed wart composition to effectively treat plantar warts. Furthermore, although Coskey does not specify the film-forming base of the podophyllin- salicylic acid-cantharidin mixture, Material Safety Data Sheet on the podophyllin- salicylic acid-cantharidin product states the active agents are in a vehicle comprising the instantly claimed acetone, benzoin, and collodion. Thus, it would have been obvious to utilize the instant composition in Johnson's device to treat plantar warts effectively.

**Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over CANTHARONE ® 1986 in view of Johnson et al (5,445,462).**

CANTHARONE comprises 0.7% cantharidin, acetone, ethocel, and flexible collodion. Cantharone is intended for the removal of warts wherein a toothpick or fine probe is used to apply a small amount of Cantharone to the surface of the wart. The product should not touch normal skin.

The product insert does not teach the instant delivery device.

Johnson teaches a liquid applicator comprising an elongated hollow body having opposed first and second open ends in fluid communication with one another, and a tip attached to the first open end and including a porous material. A closed, frangible ampoule is supported within

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the second open end of the body and contains a liquid to be dispensed. A cap is provided at the second open end of the body, and which is movable axially relative to the body between a storage position and a use position in order to fracture the ampoule. See abstract. Johnson teaches an example of a particular use for an applicator capable of applying fluid to a very small treatment area exists in the treatment of exophytic genital and anal warts. Johnson teaches that typically wart treatment includes cryotherapy with liquid nitrogen and treatment with a variety of different fluids including but not limited to Podofilox or Podophyllotoxin, silver nitrate, alcohol, TCA (trichloroacetic acid), podophyllin, or topical fluorouracil. See column 1, lines 49-67. Johnson teaches that it is known to use a toothpick or cotton-tipped swab to apply these treatments to a genital or perianal wart in an attempt to coat the wart without also applying the fluid to the surrounding skin; however it is difficult to control the amount of fluid retained on a toothpick, and a swab does not permit accurate placement onto smaller warts without also coating the surrounding skin, which causes irritation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of CATHARONE and Johnson et al and utilize the instantly claimed delivery device. One would have been motivated to do so since CATHARONE teaches applying the fluid by using a toothpick or probe and warns that the fluid should not touch normal skin and Johnson teaches a device that provides accurate treatment of warts with a medicament without the disadvantage associated with toothpicks and similar applicators.

**Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over CANTHARONE ® 1986 in view of Johnson et al (5,445,462) in further view of Huprich (5,413,780).**

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The teachings of CANTHARONE and Johnson et al have been set forth above.

The references do not teach the use of benzoin.

Huprich teaches it is well known to use film-forming substances such as tincture of benzoin to provide skin protection to wounds and prevent external contamination. Huprich teaches tincture of benzoin has been extensively used to protect the skin and increase the adhesion of other materials to the skin surface. Huprich teaches a liquid material comprising benzoin tincture and polyethylene powder to reduce abrasion and irritation to blisters, raw spots, sores, etc.. See column 1 and 2.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of CATHARONE, Johnson et al, and Huprich and further utilize benzoin in the wart composition. One would have been motivated to do so since Huprich teaches it is known in the art to utilize tincture of benzoin to not only protect that skin but also increase the adhesion of other materials to the skin. Thus it would have been prima facie obvious to further utilize benzoin for the advantages taught by Huprich.

### ***Conclusion***

All the claims are rejected at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi  
Examiner  
Art Unit 1616

